



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 18 2012

Re: PROLIA

Patent Nos.: 6,740,522; 7,097,834; and 7,411,050

Docket Nos.: FDA-2010-E-0660;

FDA-2010-E-0659; and FDA-2011-E-0014

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,740,522; 7,097,834; and 7,411,050, filed by Amgen Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for PROLIA (denosumab), the human biological product claimed by the patents.

The total length of the regulatory review period for PROLIA (denosumab) is 3,269 days. Of this time, 2,739 days occurred during the testing phase and 530 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 21, 2001.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 21, 2001.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 19, 2008.

FDA has verified the applicant's claim that the biologics license application (BLA) for PROLIA (BLA125320) was submitted on December 19, 2008.

3. The date the application was approved: June 1, 2010.

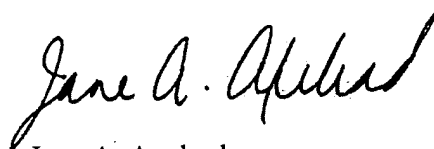
FDA has verified the applicant's claim that BLA125320 was approved on June 1, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Kappos - PROLIA
Patent Nos. 6,740,522; 7,097,834; and 7,411,050
Page 2

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad". The signature is fluid and cursive, with the first name "Jane" and last name "Axelrad" clearly distinguishable.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
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